Award Number: W81XWH-12-2-0128

TITLE: Instructive Biologic Scaffold for Functional Tissue Regeneration Following Trauma to the Extremities

PRINCIPAL INVESTIGATOR: CAPT Mark Fleming, CAPT, MC, USN

CONTRACTING ORGANIZATION: The Geneva Foundation
Tacoma, WA 98402

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14. ABSTRACT

Our hypothesis is that subjects who receive the SIS-ECM scaffold material will have significant new muscle growth and improvements in strength in the treated extremity. The proposed prospective, non-randomized, two-armed study in forty (40) subjects will establish the safety and effectiveness of a regenerative scaffold for the restoration of functional musculotendinous tissue, including the restoration of blood supply and innervation. Cohort 1 will include 20 subjects with upper extremity flexor and extensor traumatic, postoperative, or other avulsive VML. Cohort 2 will include 20 subjects with open femur fractures or soft tissue injury to the thigh resulting in VML. The primary endpoint will be changes in graft site muscle volume compared to baseline at 6 and 12 months as determined by imaging.

15. SUBJECT TERMS
Regenerative Medicine; Extracellular Matrix; Volumetric Muscle Loss

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1. INTRODUCTION: The purpose of this investigation is to evaluate the effectiveness of a regenerative biologic scaffold, Biodesign® 6-layer Plastic Surgery Matrix [Cook Biotech]; Premarket Notification Trade/Device Name: SIS Plastic Surgery Matrix, derived from small intestinal submucosa extracellular matrix (SIS-ECM), for the restoration of functional musculotendinous tissue in participants with an acute or subacute volumetric muscle loss (VML) injury. The proposed research is a prospective, multi-center, non-randomized, single-armed, two-cohort clinical trial with a targeted population of forty (40) evaluable subjects. Cohort 1 will include 20 subjects with upper extremity traumatic, postoperative, or other avulsive VML injury. Cohort 2 will include 20 subjects with lower extremity traumatic, postoperative, or other avulsive VML injury. This study will be conducted at 2 study sites: Walter Reed National Military Medical Center (WRNMMC) and the R Adams Cowley Shock Trauma Center (STC) at the University of Maryland Medical Center. Study participants will be enrolled and followed for a period of 1 year (12 months). This study will evaluate the effectiveness of Biodesign®, a 6-layer regenerative biologic scaffold derived from small intestinal submucosa extracellular matrix (SIS-ECM), for the restoration of functional musculotendinous tissue in forty (40) participants, both male and female, with an acute or subacute volumetric muscle loss (VML) defects in their upper or lower extremities. The targeted subject population will consist of injured service members or civilian victims of trauma. All subjects enrolled will receive the SIS-ECM scaffold, trimmed to fit the defect, and will serve as their own control. Only one segmental muscle defect will be treated in each subject, and each subject may receive multiple SIS-ECM grafts at the injury site. Enrolled participants will be assigned to 1 of 2 Cohort groups. Cohort 1 will include 20 subjects with upper extremity traumatic, postoperative, or other avulsive VML injury. Cohort 2 will include 20 subjects with lower extremity traumatic, postoperative, or other avulsive VML injury.

2. KEYWORDS: Regenerative Medicine; Extracellular Matrix; Volumetric Muscle Loss

3. ACCOMPLISHMENTS:
What were the major goals of the project?

Our hypothesis is that subjects who receive the SIS-ECM scaffold material will have significant new muscle growth and improvements in strength in the treated extremity. The proposed prospective, non-randomized, two-armed study in forty (40) subjects will establish the safety and effectiveness of a regenerative scaffold for the restoration of functional musculotendinous tissue, including the restoration of blood supply and innervation. Cohort 1 will include 20 subjects with upper extremity flexor and extensor traumatic, postoperative, or other avulsive VML. Cohort 2 will include 20 subjects with open femur fractures or soft tissue injury to the thigh resulting in VML. The primary endpoint will be changes in graft site muscle volume compared to baseline at 6 and 12 months as determined by imaging. Secondary endpoints will include histopathological characterization of the muscle healing response at the graft site, clinician and subject evaluation of cosmesis, and comparison of complication rates to clinical site historical standard of care.

What was accomplished under these goals?

Specific Aim 1: To induce the *de novo* formation of at least 25% of the missing muscle tissue using an inductive ECM scaffold. This tissue will be morphologically and structurally identical to native skeletal muscle tissue.

Briefly, Cook BioDesign's Plastic Surgery Matrix® device will be implanted surgically. Change in muscle volume from baseline at device implantation as determined by MRI or CT will be assessed. Biopsied tissue will be fixed and the tissue specimens will be subjected to a battery of immunohistochemical, immunolabeling, and traditional histochemical stains for the identification of cell phenotype, extracellular matrix characterization, and histomorphometric analysis. The main endpoint of this study is to determine the percentage of volume restored at the surgical site.

Task 1: IRB and Facility Approvals (months 1-4)

1a. IRB Approval (months 1-4)

Facility: Walter Reed National Military Medical Center (WRNMMC)

1b. IRB Approval (months 1-4)

Facility: Maryland Shock Trauma (MST)

1c. Approval by USAMRMC Office of Research Protections (months 4-5)

The overall study protocol is being developed and written by WRNMMC as the coordinating center and will then be sent to the MST for inclusion into their site specific protocol. MST cannot submit the protocol to the IRB, until the WRNMMC master protocol has been approved by WRNMMC's IRB Oversight Committee and DoD HRPO. The protocols are drafted and being finalized with investigators and collaborators for submission. As required prior to IRB submission, the WRNMMC protocol was submitted to the departmental Scientific Review Committee (SRC) for review and received back with minimal questions and edits. The WRNMMC protocol and CRFs are being finalized for IRB administrative and committee review. Kick-off meetings via conference call were conducted on 16 September 2014 with WRNMMC personnel and on 30 October 2014, including current PI, Mr. Janis, and transitioning PI, CDR Fleming, to discuss study roles and responsibilities. Another meeting was conducted on 13 November 2014 between WRNMMC study personnel with the addition of WRNMMC personnel Dr. Dearth and Ms. Pruziner to clarify roles. Additional meetings were conducted on 04 February 2015, 19 February 2015, 12 March 2015, 2 April 2015, 04 June 2015, 11 June 2015, 23 June 2015, 29 October 2015 with WRNMMC study personnel to discuss and clarify study protocol specifics and progress. Conference call meetings were conducted on 04 March 2015, 02 September 2015, 16 September 2015, 30 September 2015 between WRNMMC and MST, including WRNMMC PI CDR Fleming and MST PI Dr. Sciadini, to discuss study protocol and site coordination specifics. An in-person investigators' meeting between WRNMMC and MST was conducted on 27 August 2015, including WRNMMC transitioning PI, LTC Nesti, MST PI Dr. Sciadini, WRNMMC investigator Dr. Dearth, and WRNMMC and MST study coordinators, Ms. Lee and Ms. Ordonio to discuss changes in study personnel and progress. Another in-person investigators' meeting between WRNMMC and MST was conducted on 23 September 2015 at MST with Dr. Dearth and Ms. Pruziner presenting and discussing study protocol with MST investigators. A conference call meeting was conducted on 05 August 2015 with the addition of STATKING personnel to clarify roles and responsibilities. In-person meetings to discuss CRFs were conducted on 04 September 2015 with WRNMMC & MST study personnel and on 21 September 2015 with WRNMMC study personnel.

Task 2: Patient Enrollment (months 5-23)

2a. Patient Enrollment (months 5-23)

Facility: Walter Reed National Military Medical Center

2b. Patient Enrollment (months 5-23)

Facility: Maryland Shock Trauma

Clinical Patients: 40

Patient Enrollment has not yet begun.

Task 3: Patient Follow Up (months 8-31)

3a. CT Guided Biopsy (months 8-31)
Facility: Walter Reed National Military Medical Center
3b. MRI, MRI Guided Biopsy (months 8-31)
Facility: Maryland Shock Trauma
Clinical Patients: 40
Patient Follow Up has not yet begun.

Task 4: Histology/Pathology (months 8-35)
4a. Histology (months 8-35)
Facility: WRNMMC
4b. Pathology (months 8-35)
Tissue Samples: 80
Histology and Pathology has not yet begun.

Task 5: Final Report (months 35-37)
5a. Review of Data and Generation of Final Report (months 35-37)
Facility: WRNMMC
Pathology reports, functional test scores, and imaging data will be assessed by Dr. Leon Nesti and study personnel. These data will be tabulated and forwarded to the biostatistician for statistical analysis as described in the statistical plan. A final report incorporating these data will be prepared, reviewed and accepted by the PIs at WRNMMC and Maryland Shock Trauma.
Review of Data and Final Report has not yet begun.

Specific Aim 2: To restore at least 25% of the function of the involved muscle group through the use of an inductive ECM scaffold material.

Briefly, functional recovery in the injured extremity will be compared at 1, 4, 8, and 12 months. At 12 months, function of the injured extremity will be compared to the contralateral limb, if present. The main endpoint of this study is to determine the percentage of function restored to the surgical site.

Task 6: Patient Follow Up (months 8-31)
6a. Functional and Physician Assessment (months 8-31)
Facility: Walter Reed National Military Medical Center
6b. Functional and Physician Assessment (months 8-31)
Facility: Maryland Shock Trauma
Clinical Patients: 40
Patient Follow Up has not yet begun.

Task 7: Final Report (months 31-47)
7a. Review of Data and Generation of Final Report (months 31-47)
Facility: WRNMMC
Pathology reports, functional test scores, and imaging data will be assessed by the research team at WRNMMC. These data will be tabulated and forwarded to the biostatistician for statistical analysis as described in the statistical plan. A final report incorporating these data will be prepared, reviewed, and accepted by investigators.
Review of Data and Final Report has not yet begun.

What opportunities for training and professional development has the project provided?

Training and professional development activities occurred between current and former investigators and collaborators at the Military Health System Research Symposium (MHSRS), Ft Lauderdale, Florida in August 2015 and also at the Tissue Engineering and Regenerative Medicine International Society (TERMIS) World Conference, Boston, Massachusetts in September 2015.

How were the results disseminated to communities of interest?

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?

The WRNMMC protocol will be submitted for WRNMMC IRB administrative and committee review. After the WRNMMC master protocol has been approved by WRNMMC's IRB Oversight Committee and DoD HRPO, it will be sent to the MST for inclusion into their site specific protocol and MST IRB submission.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report.

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:
Changes in approach and reasons for change

Functional recovery in the injured extremity will be compared at 1, 4, 8, and 12 months as opposed to 3, 6, 9 months as originally stated in the SOW. Based on previous studies, earlier remodeling time points are of greater scientific interest.

Primary endpoint will be to restore at least 25% of the function of the involved muscle group. Secondary endpoints will include to induce the *de novo* formation of at least 25% of the missing muscle tissue using an inductive SIS-ECM scaffold, as determined by quantitative image analysis,

compared to baseline at 8 and 12 months.

Actual or anticipated problems or delays and actions or plans to resolve them
We are anticipating delays in the establishment of a CRADA due to transitioning of personnel in the CRADA office as well as transitions between current approved template standards and new DHA standards. We are working to mitigate this issue by having continuous, ongoing conversations with WR staff to ensure we are on the correct path forward and no efforts have been lost. We also anticipate changes in histology assessment due to budgetary constraints and will identify an alternate route within such budgetary constraints. Additionally, we are working to mitigate the issue of outstanding MIPR'd funds to WRNMMC for study purposes and investigating the avenues and options to resolve the matter. We are doing this by initiating conversations with DRP, Resource Management Officers on site and CDMRP to help resolve the issue. To date, we have not been able to confirm the ability to receive and route funds appropriately, but hope to have resolution to this issue in the coming months.

Changes that had a significant impact on expenditures

Due to the delay in IRB submission, anticipated costs have been significantly lower than expected. We have delayed hiring staff. Our sub recipient has also delayed their timeline and costs while we work to finalize the Coordinating Center protocol. Once these milestones have been met, we anticipate an increase in costs as the program moves forward.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

6. PRODUCTS:

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	CAPT Mark Fleming, CAPT, MC, USN
Project Role:	Principal Investigator (PI) / Site Principal Investigator at WRNMMC
Nearest person month worked:	12 months
Contribution to Project:	Dr. Fleming is an orthopedic trauma surgeon, was the site Principal Investigator (PI) at WRNMMC and then transitioned to take over the role of study PI from Abram Janis.
Name:	LTC Leon Nesti, MD, PhD LTC, MC, USA
Project Role:	Principal Investigator (PI) / Site Principal Investigator at WRNMMC

	Associate Professor, Uniformed Services University
Nearest person month worked:	2 months
Contribution to Project:	Dr. Nesti is a hand and upper extremity orthopedic reconstructive surgeon at WRNMMC who has transitioned to take over the role of study PI from Dr. Fleming, and has extensive research experience.
Name:	Marcus Sciadini, MD
Project Role:	Site Principal Investigator at MST
Nearest person month worked:	12 months
Contribution to Project:	Dr. Sciadini is an orthopedic trauma surgeon and the site Principal Investigator (PI) at MST, provided clinical expertise and input on study protocol and design.
Name:	Barry Martin, COL, MC, USA
Project Role:	Associate Investigator, Plastic & Reconstructive Surgeon
Nearest person month worked:	9 months
Contribution to Project:	Dr. Martin, is a reconstructive plastic surgeon, has provided expertise in soft tissue reconstruction, clinical applications of regenerative medicine, and provided input on study protocol and design.
Name:	Ian Valerio, MD, MS, MBA, FACS CDR, MC, USNR
Project Role:	Collaborator / Consultant
Nearest person month worked:	6 months
Contribution to Project:	Dr. Valerio, is a reconstructive plastic surgeon, former Co-Investigator (Co-I) at WRNMMC, and has provided expertise in soft tissue reconstruction, clinical applications of regenerative medicine, and provided input on study protocol and design.
Name:	Christopher Dearth, PhD
Project Role:	Associate Investigator & Subject Matter Expert at WRNMMC Facility Research Director, DoD-VA Extremity Trauma & Amputation Center of Excellence
Nearest person month worked:	11 months
Contribution to Project:	Dr. Dearth is a Scientist Subject Matter Expert at WRNMMC, facility research director, has expertise in muscle regenerative research, provided input on study protocol and design, and will assist with processing biopsies, histological evaluations and publications.
Name:	Alison Pruziner, PT, DPT, ATC
Project Role:	Associate Investigator & Research Physical Therapist at WRNMMC, DoD-VA Extremity Trauma & Amputation Center of Excellence
Nearest person month worked:	11 months
Contribution to Project:	Alison is a research physical therapist at WRNMMC, has expertise in physical therapy research, provided input on

	study protocol and design, and will assist with subject visits, functional assessments, and training PT personnel.
Name:	Shannon M. Lynch, PT, DPT, OCS LTC, SP
Project Role:	Associate Investigator, Physical Therapist & Service Chief at WRNMMC
Nearest person month worked:	12 months
Contribution to Project:	LTC Lynch is a physical therapist and service chief at WRNMMC, has expertise in physical therapy research, provided input on study protocol and design, and will assist with subject visits, functional assessments, and training PT personnel.
Name:	Michael Stidham, PT
Project Role:	Associate Investigator & Physical Therapist at WRNMMC
Nearest person month worked:	5 months
Contribution to Project:	Michael is a physical therapist at WRNMMC, has experience in physical therapy research, provided input on study protocol and design, and will assist with subject visits and functional assessments.
Name:	Caitlin Mahon, MS
Project Role:	Research Biomedical Engineer at WRNMMC, DoD-VA Extremity Trauma & Amputation Center of Excellence
Nearest person month worked:	3 months
Contribution to Project:	Nanc has performed work as a research coordinator at WRNMMC, facilitated communications between investigators, assisted with the protocol, CRFs, notes and reports.
Name:	Nancy Lee
Project Role:	Research Associate / Coordinator at WRNMMC
Nearest person month worked:	12 months
Contribution to Project:	Nancy Lee has performed work as a research coordinator at WRNMMC, facilitated communications between investigators, assisted with the protocol, CRFs, notes and reports.
Name:	Katherine Ordonio
Project Role:	Clinical Research Specialist / Coordinator at MST
Nearest person month worked:	2 months
Contribution to Project:	Katherine Ordonio has performed work as a research coordinator at MST, facilitated communications between investigators, assisted with the protocol and CRFs.
Name:	Linzie Wagner
Project Role:	Grants and Contracts Manager at the Geneva Foundation
Nearest person month worked:	12 months
Contribution to Project:	Linzie Wagner has performed work as a grants and

	contracts manager at the Geneva Foundation, managed budgets, executed subcontracts, facilitated communications between investigators and submitted reports.
Name:	Daisy Schlessinger
Project Role:	Lead Data Manager/Project Manager at STATKING Clinical Services
Nearest person month worked:	2 months
Contribution to Project:	Daisy Schlessinger has performed work providing clinical data and monitoring expertise at STATKING Clinical Services.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

There has been a change in PI that occurred in Year 1, Quarter 4. Principal Investigator, CAPT Mark Fleming, received a transfer within the Navy to the University of Southern California and left Walter Reed National Military Medical Center effective September 2015. A request to change the PI on this award from CAPT Fleming to LTC Leon Nesti was submitted on 25 August 2015 to the sponsor. LTC Nesti is a hand and upper extremity orthopedic reconstructive surgeon at WRNMMC, Associate Professor and Chief of Clinical and Experimental Orthopaedics at Uniformed Services University. Dr. Nesti's current and past clinical and research experience is well-suited for this trial and a smooth transition is anticipated. Dr. Nesti's Bio, CV, and Support documents are attached for reference (see Appendix A-C).

Associate Investigator, CDR Ian Valerio, left Walter Reed National Military Medical Center effective December 2014 and transitioned from Navy active duty to Navy reserves.

Initial PI, Abram Janis, left the project and transferred the PI to CDR Mark Fleming in December 2014. A request to change the PI this award from Mr. Janis to CDR Fleming was submitted on 05 December 2014 to the sponsor. Mr. Janis provided a letter of support and relinquishment as PI and CDR Fleming provided the signed PI Safety Assurance. Approval for the modification requesting the change of PI was received on 28 January 2015.

What other organizations were involved as partners?

Organization Name: The Geneva Foundation
Location of Organization: 917 Pacific Ave, Suite 600 Tacoma, WA 98402
Partner's contribution to the project: Financial support (i.e. grants and contracts management)

Organization Name: R Adams Cowley Shock Trauma Center (STC), University of Maryland Medical Center
Location of Organization: 22 S. Greene Street, Baltimore, MD 21201
Partner's contribution to the project: Facilities (i.e. external site - subaward was submitted to MST on 03 December 2014 and was executed on 15 April 2015); Collaboration (i.e. partner's staff work with project staff on the project); Personnel exchanges (i.e. project staff will work with partner's staff at external site)

Organization Name: STATKING Clinical Services
Location of Organization: 759 Wessel Drive, Fairfield, OH 45014

Partner's contribution to the project: Collaboration (i.e. partner's staff work with project staff on the project); Clinical Monitoring & Data Management

Organization Name: Cook Biotech, Inc.
Location of Organization: 1425 Innovation Place, West Lafayette, IN 47906
Partner's contribution to the project: Vendor (Instructions For Use (IFU) for Biodesign® Plastic Surgery Matrix was obtained from Cook® Medical on 07 May 2015)

5. SPECIAL REPORTING REQUIREMENTS: None

APPENDICES:

- **Appendix A: Dr. Nesti's Bio**
- **Appendix B: Dr. Nesti's CV**
- **Appendix C: Dr. Nesti's Support**

LTC Leon Nesti, MD, PhD: Dr. Leon Nesti received his BS from the United State Military Academy at West Point, and his MD PhD through the clinician-scientist training program at Thomas Jefferson University and Jefferson Medical College. After completing his Orthopaedic Surgery residency at Walter Reed Army Medical Center, Dr. Nesti continued his subspecialty training in Hand and Upper Extremity Reconstructive Surgery in the combined Walter Reed, Curtis National Hand Center program. Dr. Nesti served as the Chief of the Orthopaedic Research Group at the National Institutes of Health/National Institute of Arthritis and Musculoskeletal and Skin Diseases and now serves as the Chief of Clinical and Experimental Orthopedics Laboratory at the Uniformed Services University of the Health Sciences. He is a Hand and Upper Extremity Reconstructive surgeon at Walter Reed National Military Medical Center and performs duties as the Co-Surgical Chief of the Walter Reed Peripheral Nerve Clinic and the Upper Extremity consultant for the United States Military Academy and its athletic teams. He is an active participant in the Army's PROFIS system and recently returned from Afghanistan where he functioned as the 936 Forward Surgical Team's Orthopaedic Surgeon. Dr. Nesti's clinical and scientific interests are focused on progenitor cell function in musculoskeletal disease and regeneration.

Curriculum Vitae

Leon J. Nesti, MD PhD
LTC, MC
(July 2015)

CONTACT INFORMATION

	Work
	Uniformed Services University "America's Medical School" 4301 Jones Bridge Road Bethesda, MD 20814 (240) 994-7347 (Fax) (301) 295-3157 leonnesti@gmail.com leon.j.nesti.mil@mail.mil leon.nesti@usuhs.edu

EDUCATION

BACHELOR OF SCIENCE (ACS CHEMISTRY) – 1995
United States Military Academy, West Point, New York

DOCTOR OF MEDICINE – 2002
Jefferson Medical College of Thomas Jefferson University
Philadelphia, PA

DOCTOR OF PHILOSOPHY – 2000
College of Graduate Studies of Thomas Jefferson University

PROFESSIONAL SOCIETIES

Association of Graduates, United States Military Academy – 1995
American Society of Cell Biology – 1998 to Present
Orthopaedic Research Society – 2001 to Present
Society of Military Orthopaedic Surgeons – 2001 to Present
American Military Surgeons of the United States – 2002
American Academy of Orthopaedic Surgery - 2012 to Present

American Society for Bone and Mineral Research – 2003 to Present
American Society for Surgery of the Hand – 2013 to Present
American Orthopaedic Association -- 2015 to Present

CERTIFICATION AND TRAINING

Master Fitness Trainer – 1995
NAUI Dive Certification – 1995
Basic Life Support – 2001
Advanced Cardiac Life Support - 2001
USMLE Steps I-III Pass
ABOS Diplomat 2012

Appointments

Program Director, Walter Reed Section
Combined Walter Reed/Curtis National Hand Center Hand Fellowship
Walter Reed National Military Medical Center
Bethesda, MD May 2015-Present

Chief, Clinical and Experimental Orthopaedics
Department of Surgery
Uniformed Services University of the Health Sciences
Bethesda, MD Oct 2014-Present

Chief, Clinical and Experimental Orthopaedics
National Institute of Arthritis, and Musculoskeletal & Skin Diseases
National Institutes of Health
Bethesda, MD Aug 2009-2014

Associate Professor
Department of Surgery
Uniformed Services University of the Health Sciences
Bethesda, MD February 2014- Present

Assistant Professor
Department of Surgery
Uniformed Services University of the Health Sciences
Bethesda, MD February 2005-2014

Special Volunteer
National Institute of Arthritis, and Musculoskeletal & Skin Diseases
National Institutes of Health
Bethesda, MD June 2004-2009

Guest Investigator
NMRC
Silver Spring, MD January 2005- 2008

Clinical Instructor
Uniform Services University of the Health Sciences
Bethesda, Maryland October 2002- 2005

POSITIONS

Billeted Faculty
Department of Surgery
Uniformed Services University of the Health Sciences
Bethesda, MD
Aug 2011-Present

Adjunct Principle Investigator
National Institute of Arthritis, and Musculoskeletal & Skin Diseases
National Institutes of Health
Bethesda, MD
Aug 2009-2014

Hand and Upper Extremity Reconstructive Surgeon
United States Military Academy at West Point
Aug 2010-Present

Hand and Upper Extremity Reconstructive Surgeon
Kimbrough Ambulatory Care Center
Ft. Meade, MD
October 2010 - Present

Hand and Upper Extremity Reconstructive Surgeon
Walter Reed National Military Medical Center
Bethesda, MD
October 2010 - Present

Hand and Upper Extremity Reconstructive Surgeon
McDonald Army Health Clinic
Ft. Eustis, VA
Aug 2009-Aug 2011

Hand and Upper Extremity Reconstructive Surgery Fellow
Curtis National Hand Center, Baltimore, MD
Walter Reed Army Medical Center, Washington, DC
Aug 2008-Aug 2009

Orthopaedic Surgery Resident
Walter Reed Army Medical Center
Washington, D.C. June 2002-June 2008

Postdoctoral Fellow
National Institutes of Health
National Institutes of Arthritis, musculoskeletal and skin Diseases
Cartilage Biology and Orthopaedics Branch
Washington, D.C. June 2004-June2005

Graduate Student, Doctor of Medicine
Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania, August 1995 – June 2002

Graduate Student, Doctor of Philosophy
College of Graduate Studies of Thomas Jefferson University
Philadelphia, Pennsylvania, August 1995 – June 2002

Cadet, United States Military Academy
West Point, New York, July 1991 – June 1995

MILITARY EXPERIENCE

Education:	Captain's Career Course - 2010
	Combat Casuality Care Course- 2002
	AMEDD Officer Basic Course – 1996
Awards:	National Defense Service Medal
	Army Service Ribbon
	Army Achievement Medal
	Army Commendation Medal
	Global War on Terrorism
	NATO Medal
	Afghanistan War Medal
Deployment:	936th Forward Surgical Team, Meymaneh, Afghanistan 2011

AWARDS

United States Bone and Joint Decade Young Investigator Award 2007.

Society of Military Orthopaedic Surgerons, Founder's Award 2006.
"Activin Receptor Expression in Heterotopic Ossification"

Washington Orthopaedic Society Resident Research Award, 2005. Nesti LJ, Li WJ, Freedman BA, Shanti RM, Jiang YG, Kuklo TR, Tuan RS. "The Potential of a Novel Hyaluronic Acid Nanofibrous Scaffold (HANFS) Amalgam in Intervertebral Disc Tissue Engineering."

Huffnagel Award, U.S. Army Basic Science Research Award, 2005. Nesti LJ, Li WJ, Freedman B, Jiang Y, Kuklo TR, Tuan RS. "Novel Tissue Engineered Intervertebral Disc Construct Supports Stem Cell Growth and Differentiation."

AAOS/OREF Clinician Scientist Development Award, 2005.

Hyman Menduke Research Prize. Recognition for outstanding Research performed while a medical student at Jefferson Medical College. June 2002

New Investigator Recognition Award (NIRA). Orthopaedic Research Society 48th annual meeting, February 2002.

Army Health Profession Scholarship (HPSP)
Tuition, supplies, and stipend support for studies leading to a M.D. degree. 1995-2002

Office of the Dean Travel Award: 2000 – Thomas Jefferson University. Presented to a deserving medical student who has had his research accepted for presentation at a national meeting.

Jefferson Alumni Travel Award: 1999 – Thomas Jefferson University. Presented to a deserving graduate student who has had his research accepted for presentation at a national meeting.

GRANTS/FUNDING

Clinical Evaluation of Decellularized Nerve Allograft with Autologous Bone Marrow Stem Cells to Improve Peripheral Nerve Repair and Functional Outcomes CDMRP, MR140132 2015-2018 (PI - $2,500,000)

Early Identification of Molecular Predictors of Heterotopic Ossification following Extremity Blast Injury: Animal Model Correlation with Human Disease. CDMRP, OR120071P1. 2013-2016. (Partnering-PI - $450,000)

Mesenchymal Progenitor Cell Therapy in the Prevention of Tissue Fibrosis, DMRDP, D10-I-AR-J8-981 2011-Present. (PI - $750,000)

Virtual Stress Test of Healing Fractures, G190VV USAMRRA 2010-2014 (PI – $110,000)

Stem Cell Based Neurotrophic Enhancement of an Aligned Nanofiber Scaffold for Nerve Repair USAMRAA 304914-1-63348 2011-2014 (PI – $313,643).

Mechanisms of Heterotopic Ossification. National Insititues of Health, National Institute of Arthritis and Musculoskeletal and Skin Diseases. ZIA AR041191 2009-present.

Congressionally Directed Medical Research Program "Small Molecule Therapy in the Prevention of Heterotopic Ossification" 00519318 , 2009-2010, (PI- $150,000).

Comprehensive Neuroscience Program, "Evaluation of a Nanoscale Peripheral Nerve Conduit", 2008-2010, (PI - $300,000).

Musculoskeletal Transplant Foundation, "A Novel Biomimetic Allograft Bone Powder-Nanofibrous Scaffold Bone Substitute.", 2007-2008, (PI - $120,000).

Military Amputee Research Program, Walter Reed Army Medical Center, "Mechanism of in the Military Amputee Population"
Log # PO5-A011, 2006-2008, (PI - $600,000).

National Institutes of Health, MD, PhD Predoctoral Fellowship
Medical Scientist Training program providing tuition, research supplies, and stipend support for studies leading to a combined M.D./Ph.D. degree.
NIH-NRSA F30AA05516, 1997-2001

DOCTORAL DISSERTATION

Nesti, LJ. 2000 *Identification and Characterization of a Novel TGF-beta1 Calcium Signaling Pathway in Human Osteoblasts.* **Doctoral Thesis,** Thomas Jefferson University.

JOURNAL ARTICLES (Published/Accepted):
h-index: 22

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1. Nesti LJ, Chang R, Zapatero JM, Hoek JB, Tuan RS. 1999 *TGF-b1 Stimulation Elicits an Intracellular Calcium Signal in Osteoblasts.* **Jeff Orthop J** 28:76-80.

ABSTRACT PUBLICATIONS

1. Jones PE, Bharmal H, Ji Y, Christopherson G, Hall D, Nesti LJ. Microstructure Of Traumatized Muscle From Blast Injuries Enhances Osteogenesis. 60th Annual Meeting of the ORS, March 15-18, 2014, New Orleans, LA.
2. Jones PE, Bharmal H, Ji Y, Christopherson G, Hall D, Jackson WM, Robertson A, Pellegrini VD, Nesti LJ. Clinical Validation Of An In Vivo Rat Model For The Study Of Blast-induced Heterotopic Ossification. 60th Annual Meeting of the ORS, March 15-18, 2014, New Orleans, LA
3. Christopherson G, Bharmal H, Ji Y, Cirino C, Jackson W, Nesti L. Characterization of Microenvironment of Traumatized Muscle Tissue in the Study of Heterotopic Ossification. Annual NIAMS IRP Scientific Retreat, May 2013, Bethesda MD
4. Bharmal H, Ji Y, Christopherson G, Nguyen T, Robertson A, Cirino C, Jackson W, Pellegrini V, Nesti L. Heterotopic Ossification: An in vivo Rat Model. Annual NIAMS IRP Scientific Retreat, May 2013, Bethesda MD
5. Ji Y, Shin E, Kluk M, Vogler J, Bharmal H, Cirino C, Patel N, Jackson W, Nesti L. Identification and Validation of a miRNA Signature Associated with Heterotopic Ossification after Orthopaedic Combat Blast Injury. Annual NIAMS IRP Scientific Retreat, May 2013, Bethesda MD
6. Cirino C, Patel N, Shin E, Christopherson G, Shin D, Jackson W, Ji Y, Nesti L. Establishment of an in vitro Fibroproliferative Model Elucidating Heterotopic Ossification after War Blast Injury. Annual NIAMS IRP Scientific Retreat, May 2013, Bethesda MD
7. Ji Y, Christopherson G, Bharmal H, Shin E, Cirino C, Patel N, Jackson W, Nesti L. Molecular analysis of mesenchymal progenitor cells derived from war-traumatized muscle tissue. 2013 NIH CRM / SCIG Stem Cell Research Symposium, May 2013, Bethesda MD

8. Bharmal H, Christopherson G, Ji Y, Cirino C, Jackson W, Nesti L. An Innovative Culture System to Study Heterotopic Ossification. Virginia Orthopaedic Society, May 2013, Washington DC
9. Shin E, Ji Y, Christopherson G, Bharmal H, Jackson W, Nesti L. An In Vitro Fibroproliferative Model to Investigate Cellular Precursors of Heterotopic Ossification. Virginia Orthopaedic Society, May 2013, Washington DC
10. Shin E, Ji Y, Christopherson G, Bharmal H, Jackson W, Nesti L. An In Vitro Fibroproliferative Model to Investigate Cellular Precursors of Heterotopic Ossification. American Academy of Orthopaedic Surgeons, March 2013, Chicago IL
11. Bharmal H, Christopherson G, Ji Y, Cirino C, Jackson W, Nesti L. An Innovative Culture System to Study Heterotopic Ossification. Orthopaedic Research Society, January 2013, San Antonio TX
12. Shin E, Ji Y, Christopherson G, Bharmal H, Jackson W, Nesti L. An In Vitro Fibroproliferative Model to Investigate Cellular Precursors of Heterotopic Ossification. Society of Military Orthopaedic Surgeons, December 2012, Naples FL
13. Shin DH, Shin EH, Christopherson G, Cirino CM, Jackson WM, Ji Y, Nesti LJ. Investigating an in vitro fibroproliferative model for heterotopic ossification in war traumatized muscle injury. 2012 NIH Summer Poster Day, August 9th, in the Natcher Conference Center #444.
14. McShane AJ, Ji Y, Nesti LJ. Utilizing Mass Spectrometry-Based Proteomics to Validate miRNA Gene Targets in Post-Traumatic Heterotopic Ossification. 2012 NIH Summer Poster Day, August 9th, in the Natcher Conference Center #440.
15. Bell S, Ji Y, Lopez MP, Nesti LJ. Heterotopic Ossification: Determining the Significance of TGFB1/TGFB3 Ratio. 2012 NIH Summer Poster Day, August 9th, in the Natcher Conference Center #434.
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23. JacksonWM, Lozito TP, Djouad F, Tuan RS, Nesti LJ. Pro-Regenerative Functions of Mesenchymal Progenitor Cells Derived from Traumatically Injured Muscle. Trans. Orthopaedic Research Society Annual Conference 2010. New Orleans, LA. # 733.
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33. Jackson WM, Aragon AB, Koehler SM, Giuliani JR, Nesti LJ, Tuan RS. Progenitor cells derived from traumatically injured muscle tissue exhibit limited osteogenic differentiation potential. Trans Ortho Res Soc, 2008. San Francisco, CA. #828.

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40. Nesti LJ, Jackson W, Giuliani JR, Freedman BA, Li WJ, Tuan RS 2007 Human Skeletal Muscle Derived Stem Cells From a Direct Plating Technique. Transactions Orthopaedic Research Society 53rd Annual Meeting, Vol 32.
41. Steinbeck MJ, Nesti LJ, Sharkey PF, Parvizi J. 2006 Myeloperoxidase and Chlorinated-peptides in Osteoarthritis: Potential Biomarkers of the Disease. American Society of Bone and Mineral Research (ASBMR).
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45. Nesti LJ, Li WJ, Freedman BA, Jiang Y, Kuklo TR, Tuan RS. 2005 Novel Nanofibrous Intervertebral Disc Construct Supports Cell Growth and Matrix Production North American Spine Society (NASS).
46. Nesti LJ, Shanti RM, Li WJ, Jiang Y, Tuan RS. 2005 Multipotential Cells Derived from Human Skeletal Muscle National Institute of Arthritis and Musculoskeletal and Skin Diseases Retreat.
47. Shanti RB, Li WJ, Nesti LJ, Tuan RS. 2005 A Three-Dimensional Nanofibrous Scaffold for Skeletal Muscle Tissue Engineering Using Human Bone Marrow

Derived Mesenchymal Stem Cells National Institute of Arthritis and Musculoskeletal and Skin Diseases Retreat.

48. Nesti LJ, Li WJ, Freedman BA, Jiang Y, Kuklo TR, Tuan RS. 2005 A Novel Nanofiber-Gel Scaffold for Use in Intervertebral Disc Tissue Engineering. Soc Mil Orthop Surg.
49. Kuklo TR, Potter BK, Lenke LG, Nesti LJ 2005 Thoracic Vertebral Rotation in Adolescent Idiopathic Scoliosis: What is the Best Plain Radiographic Correlate of Postoperative Derotation? Soc Mil Orthop Surg.
50. Nesti LJ, Caterson EJ Wang M, Chang R, Chapovsky F, Hoek JB, Tuan RS 2002 TGF-b1 Intracellular Signaling: Crosstalk Between Intracellular Calcium and MAPK. Trans ORS 48:322.
51. Nesti LJ, Caterson EJ, Wang M, Chang R, Chapovsky F, Hoek JB, Tuan RS 2001 TGF-b1 Stimulated Osteoblasts Require Intracellular Calcium Signaling For Enhanced a5 Integrin Expression. NIH BECON "Reparative Medicine: Growing Tissues and Organs".
52. Caterson, EJ, Li, WJ, Nesti LJ, Albert T, Danielson K , Tuan RS 2001 Polymer/Alginate Amalgam for Cartilage Tissue Engineering. NIH BECON "Reparative Medicine: Growing Tissues and Organs".
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54. Caterson, EJ, Li WJ, Nesti LJ, Strachan G, Albert T, Danielson K, Tuan R S 2001 Chondrogenic Differentiation and Proliferation Properties of Human Mesenchymal Stem Cells on PLA Polymer Scaffolds and PLA Polymer/Alginate Amalgams. Trans ORS 47:602.
55. Caterson E.J, Li W J, Nesti L J, Albert T, Danielson K, Tuan RS Chondrogenic Tissue Engineering Constructs of Human Marrow Stromal CellsLoaded into PLA and PLA/Alginate Amalgams Advances in Tissue Engineering for the treatment of Arthritic Dieases. Sept. 11, 2000 Boston MA.
56. Nesti LJ, McCann TM, Tuan RS, Hoek 2000 Ethanol Inhibits TGF-b1Iinduced Intracellular Calcium Signal in Primary Human Osteoblasts. Sigma Xi, Thomas Jefferson University.
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58. Nesti LJ, Chang R, Zapatero JM, Hoek JB, Tuan RS, 1998 TGF-b1 Stimulated Intracellular Calcium Signal is Required for Osteoblast Adhesion Enhancement. Cell Biol.

PODIUM PAPER PRESENTATIONS

1. Shin E, Ji Y, Christopherson G, Bharmal H, Jackson W, Nesti L. An In Vitro Fibroproliferative Model to Investigate Cellular Precursors of Heterotopic Ossification. Maryland Orthopaedic Association, April 2013, Baltimore MD
2. Bharmal H, Christopherson G, Ji Y, Cirino C, Jackson W, Nesti L. An Innovative Culture System to Study Heterotopic Ossification. Maryland

Orthopaedic Association, April 2013, Baltimore MD *Recognized for 1st place Resident Research Award

3. Shin E, Ji Y, Christopherson G, Bharmal H, Jackson W, Nesti L. An In Vitro Fibroproliferative Model to Investigate Cellular Precursors of Heterotopic Ossification. Society of Military Orthopaedic Surgeons, December 2012, Naples FL
4. Nesti LJ, Ji Y, Christopherson GT, Hall D, Vogler J, Kluk MW, Shin EH, Jackson WM, Nesti LJ. *The Pathophysiology of Heterotopic Ossification: Dysregulation of Tissue Repair and Regeneration.* Trans Orthopaedic Research Society Annual Conference 2012. San Francisco, CA.
5. Ji Y, Shin EH, Vogler J, Kluk MW, Jackson WM, Nesti LJ. Finding *Molecular Targets of Heterotopic Ossification Following War Trauma Using microRNA.* Trans Orthopaedic Research Society Annual Conference 2012. San Francisco, CA.
6. Jackson WM, Hoover JB, Aragon AB, Onodera J, Nesti LJ, Tuan RS. *Progenitor Cells Harvested from Human Muscle Exhibit Enhanced Osteogenic Potential Following Traumatic Injury.* **Trans. Orthopaedic Research Society Annual Conference 2009**. Las Vegas, NV, #170
7. Onodera J, Jackson WM, Aragon AB, Nesti LJ, Tuan RS. *Heterotopic Ossification Within Injured Muscle: Localizing the Expression of Osteogenic Genes*. **Trans. Orthopaedic Research Society Annual Conference 2009**. Las Vegas, NV, #354
8. Nesti LJ, Li WJ, Freedman BA, Shanti RM, Jiang YG, Kuklo TR, Tuan RS. 2005 *The Potential of a Novel Hyaluronic Acid Nanofibrous Scaffold (HANFS) Amalgam in Intervertebral Disc Tissue Engineering.* **Washington Orthopaedic Society**.
9. Nesti LJ, Li WJ, Freedman B, Jiang Y, Kuklo TR, Tuan RS. 2005 *Novel Tissue Engineered Intervertebral Disc Construct Supports Stem Cell Growth and Differentiation.* **Uniformed Services University for the Health Sciences Surgical Associates Society**.
10. Freedman BA, Potter BK, Nesti LJ, Cho T, Kuklo TR 2005 *Osteoporosis and Distal Radius Fractures: Continued Missed Opportunities* **Amer Acad Orthop Surg.**
11. Nesti LJ, Caterson EJ, Wang M, Chang R, Chapovsky F, Hoek JB, Tuan RS 2001 *TGF-b1 Signaling Mechanics in Human Osteoblasts.* **Soc Mil Orthop Surg** 43:25.
12. Nesti LJ, Caterson EJ, Chang R, Hoek JB, Tuan RS 2001 *TGF-b1 Calcium Signal Increases a5 Integrin Expression and Cell Proliferation in Human Osteoblasts.* **Trans ORS** 47:100.
13. Nesti LJ, Caterson EJ, Chang R, Chapovsky F, Wang M, Hoek JB, Tuan RS 2000 *TGF-b1 Calcium Signal Increases a5 Integrin Expression in Osteoblasts.* **Soc Mil Orthop Surg** 42:49.
14. Nesti LJ, McCann TM, Anderson P, Hoek JB, Tuan RS. 2000 *Mechanisms of TGF-b1 Calcium Signaling in Primary Human Osteoblasts.* **Trans ORS** 46:97.

INVITED LECTURES

1. Nesti LJ, Murphy KP 2005 *Musculoskeletal Knee and Joint Conditions.* **American College of Occupational and Environmental Medicine (ACOEM)** Washington, DC, USA.
2. Nesti LJ, Li WJ, Shanti RM, Tuan RS. 2005 *Novel Nanofibrous Constructs in Orthopaedic Tissue Engineering.* **Regenerative Medicine Institute (REMEDI), National University of Ireland** Galway, Ireland.
3. Nesti LJ, 2005 *Heterotopic Ossification in Orthopaedic Trauma.* **Regenerative Medicine Institute (REMEDI) Grand Rounds, National University of Ireland** Galway, Ireland.
4. Nesti LJ, 2006 The Stem Cell in Spine Surgery. **American College of Spine Surgeons** Boulder, CO, USA.
5. Nesti LJ, 2007 Stem Cells in Spine Surgery**. American College of Spine Surgery, Nashville,** TN, USA.
6. Nesti LJ, 2010 Progenitor Cells in their Traumatic Niche. 20-21 Oct 2010 **Conference on Human Cell Transformation: Role of Stem Cells in the Microenvironment. McGill University,** Montreal, CA.
7. Nesti LJ, 2011 Muscle Injury, Repair and Regeneration **Quality of Healing: Defining and Quantifying Healing. Brigham and Womens Hospital, Harvard Medical School**, Boston, MA.
8. Nesti LJ, 2011 Initial Management of the Mangled Hand **Orthopaedic Surgery Grand Rounds, Mayo Clinic,** Rochester, MN.
9. Nesti LJ, 2011 Post-Traumatic Heterotopic Ossification **Orthopaedic Research Grand Rounds, Mayo Clinic,** Rochester, MN.
10. Nesti LJ, 2012 Cellular and Molecular Mechanisms of Heterotopic Ossification **Uniformed Services University Surgical Associates Day**, Bethesda, MD.
11. Nesti LJ, 2012 Initial Management of the Mangled Hand and Basic Science Investigation of Tissue Repair and Regeneration. **Brigham and Women's Hospital Grand Rounds, Harvard Medical School**, Boston, MA.

BOOK CHAPTERS

1. Nesti LJ, Kuklo TR, Caterson EJ "Cells, Signals, and Scaffolds: The Future of Spinal Fusion", 2003 In Advances in Spinal Fusion: Molecular Science, Biomechanics, and Clinical Management, edited by K Lewandroski, DL Wise, DJ Trantolo, MJ Yaszemski, AA White , 649-668, New York:Marcel Dekker Inc.
2. Ji Y, Christopherson G, Kluk M, Amrani O, Jackson WM, Nesti LJ "Heterotopic Ossification Following Musculoskeletal Trauma: Modeling Stem and Progenitor Cells in their Microenvironment" 2011 In Human Cell Transformation.

3. Vogler J, Jackson WM, Nesti LJ "Tissue Engineering and Regeneration" 2011 in Combat Orthopaedic Surgery: Lessons Learned in Iraq and Afghanistan.
4. Freedman BA, Nesti LJ "Management of Complex Combat-Related Soft Tissue Wounds/Negative Pressure Wound Therapy" 2011 in Combat Orthopaedic Surgery: Lessons Learned in Iraq and Afghanistan.
5. Nesti LJ, Wolf JM, Shin EH "Elbow, Wrist and Hand Injuries" 2015 in Musculoskeletal Injuries in the Military

Professional Society Activities

1. Moderator, Growth Factors, 49th Annual Meeting of the Orthopaedic Research Society 2003.
2. Scientific Abstract Reviewer, 51st Annual Meeting of the Orthopaedic Research Society 2005.
3. Moderator, Stem Cells, 51st Annual Meeting of the Orthopaedic Research Society, 2005.
4. Scientific Abstract Reviewer, 52nd Annual Meeting of the Orthopaedic Research Society 2006.
5. Moderator, Intervertebral Disc, 52nd Annual Meeting of the Orthopaedic Research Society 2006.
6. Grant Reviewer, Musculoskeletal Transplant Foundation 2007.
7. Manuscript Reviewer Journal of Immunopharmicology 2007 - Present.
8. Manuscript Reviewer Journal of Orthopaedic Research 2007 - Present.
9. Orthopaedic Research Society, Media Relations Committee 2010-2014.
10. ASSH Research Management Committee. 2010-2014.
11. Chair, ASSH Research Management Committee 2014-Present
12. Scientific Reviewer, Congressionally Directed Medical Research Programs, 2010- Present.
13. Scientific Reviewer, Armed Forces Institute of Regenerative Medicine II. Fall 2012.
14. Manuscript Reviewer PLOS One 2014-Present

USUHS Activities

1. 27 March 2005, Orthopaedic Orientation Class.
2. 2003-2008, Orthopaedic Pearls Class (provided to 3rd and 4rth year medical students during their Orthopaedic rotations)
3. April 2007 – Present, Mentor Orthopaedic Research Lab
4. December 2007, Introduction to Orthopaedic Physical Exam.
5. Co-Director USUHS Microvascular Surgery Course 2012-Present.
6. Space Committee Member 2014-Present

PATENTS

1. Tuan RS, Caterson EJ, Li WJ, Nesti LJ 2001 *Bio-reasorbable Polymer/Alginate Amalgam Cell Construct for Cartilage Tissue Engineering* Provisional Patent Application. Registration #: 42,215 Docket # TUA 01-P0002.
2. Li WJ, Nesti LJ, Tuan RS 2006 *Cell-Nanofiber Composite and Cell-Nanofiber Composite Amalgam Based Engineered Intervertebral Disc.* DHHS Reference No. E-309-2006/1, U.S. Provisional Application No. 60/848,284 filed 28 Sep 2006
3. Nesti LJ, Jackson WM, Tuan RS. *A nanofiberous conduit seeded with muscle-derived mesenchymal progenitor cells as trophic mediators for peripheral nerve regeneration.* November 26, 2008, US 8,652,458 B2

Previous, Current, and Pending Support

Previous Support

PI: Dr. Leon Nesti
Title: Mechanism of in the Military Amputee Population
Time Commitment:
Supporting Agency: Military Amputee Research Program, Walter Reed Army Medical Center
Funding Agency's Procuring Contracting/Grants Officer:
Performance Period: 2006 - 2008
Level of Funding: $600,000
Project Goal:
Role: PI

PI: Dr. Leon Nesti
Title: A Novel Biomimetic Allograft Bone Powder-Nanofibrous Scaffold Bone Substitute
Time Commitment:
Supporting Agency: Musculoskeletal Transplant Foundation
Funding Agency's Procuring Contracting/Grants Officer:
Performance Period: 2007-2008
Level of Funding: $120,000
Project Goal:
Role: PI

PI: Dr. Leon Nesti
Title: Evaluation of a Nanoscale Peripheral Nerve Conduit
Time Commitment:
Supporting Agency: Comprehensive Neuroscience Program
Funding Agency's Procuring Contracting/Grants Officer:
Performance Period: 2008 - 2010
Level of Funding: $300,000
Project Goal:
Role: PI

PI: Dr. Leon Nesti
Title: Small Molecule Therapy in the Prevention of Heterotopic Ossification
Time Commitment: 0.6 calendar months
Supporting Agency: DRMRP
Funding Agency's Procuring Contracting/Grants Officer:
Sudha Srinagesh
Vice President for Research Administration Services
Henry M. Jackson Foundation
1401 Rockville Pike, Suite 600
Rockville, MD 20852-1402
(301) 294-1276
ospnga@hjf.org
Performance Period: 2009 - 2010
Level of Funding: $150,000
Project Goal: The aim of this project is to test the hypothesis that treatment with Dorsomorphin will make up for failures in endogenous BMP signaling attenuation mechanisms that occur in the traumatically injured muscle and lead to heterotopic ossification.

Role: PI

PI: Dr. Leon Nesti
Title: Virtual Stress Test of Healing Fractures
Time Commitment:
Supporting Agency: USAMRRA

Funding Agency's Procuring Contracting/Grants Officer:

Performance Period: 2010-2014
Level of Funding: $110,000
Project Goal:
Role: PI

PI: Dr. Leon Nesti
Title: Stem Cell Based Neurotrophic Enhancement of an Aligned Nanofiber Scaffold for Nerve Repair
Time Commitment: 1.2 calendar months
Supporting Agency: USAMRAA

Funding Agency's Procuring Contracting/Grants Officer:

Thomas Scofield
Vice President Business Development
Henry M. Jackson Foundation
1401 Rockville Pike, Suite 600
Rockville, MD 20852-1402
(301) 294-1243
tscofield@hjf.org
Performance Period: 2011-2014
Level of Funding: $313,643
Project Goal: The goal of this project is to test the hypothesis that mesenchymal progenitor cells derived from traumatized muscle and seeded within a biodegradable scaffold consisting of aligned nanofibers are capable of providing neurotrophic enhancement of nerve regeneration by generating a biochemical bridge that promotes axonal growth and migration of cells that promote regeneration.
Role: PI

Current Support
PI:
Title: Mechanisms of Heterotopic Ossification.
Time Commitment:
Supporting Agency: NIH

Funding Agency's Procuring Contracting/Grants Officer:

Performance Period: 2009 - Present
Level of Funding:
Project Goal:
Role:

PI: Dr. Leon Nesti
Title: Mesenchymal Progenitor Cell Therapy in the Prevention of Tissue Fibrosis
Time Commitment: 2 calendar months
Supporting Agency: DMRDP

Funding Agency's Procuring Contracting/Grants Officer:

Robyn Strachan
Budget Officer

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Office of the Director
31 Center Drive
Bethesda, MD 20892-2350
(301) 496-5521
strachar@mail.nih.gov
Performance Period: 2011-Present
Level of Funding: $750,000
Project Goal: The goal of this project is to test the hypothesis that autologous MPCs derived from traumatically injured muscle are a safe, effective and convenient cell type for cell-based therapy to prevent scar tissue formation following trauma-related orthopaedic injury.
Role: PI

PI: Dr. Leon Nesti
Title: Early Identification of Molecular Predictors of Heterotopic Ossification following Extremity Blast Injury: Animal Model Correlation with Human Disease
Time Commitment:
Supporting Agency: CDMRP
Funding Agency's Procuring Contracting/Grants Officer:
Performance Period: 2013 - 2016
Level of Funding: $450,000
Project Goal:
Role: Partnering PI

PI: Dr. Leon Nesti
Title: Instructive Biologic Scaffold for Functional Tissue Regeneration Following Trauma to the Extremities
Time commitments: 1.2 Calendar Months
Supporting Agency: CDMRP
Name/Address of the Funding Agency's Procuring Contracting/Grants Officer: N/A
Performance Period: 9/3/2014-8/31/2017
Funding: $1,487,923.08
Goal: The proposed clinical trial will establish the effectiveness of a UBMECM scaffold for the restoration of functional skeletal muscle tissue, including the restoration of blood supply and innervation. Successful completion of our objectives would provide a regenerative alternative to the current standard of care for extremity VML and restore quality of life to injured war fighters. We hypothesize that subjects who receive the UBM-ECM scaffold in the acute and subacute post-injury periods will have significant new muscle growth and improvements in strength in the treated extremity.
List of Specific Aims:
Specific Aim 1: To induce the de novo formation of at least 25% of the missing muscle tissue using UBM- ECM.
Specific Aim 2: To restore at least 25% of the function of the involved muscle group.
Role: Co-Principal Investigator

PI: Dr. Leon Nesti
Title: Dermal Coverage of Traumatic War Wounds
Time Commitment: 1.2 calendar months
Supporting Agency: CDMRP
Name and Address of Funding Agency's Procuring Contracting/Grants Officer:
Sandra Rosario
U.S. Army Medical Research Acquisition Activity Grant Specialist - Gold Team
843 Chandler Street
Fort Detrick, MD 21740

T: 301-619-4063
sandra.rosario@amedd.army.mil
Performance Period: 10/31/2012-10/30/2016
Funding: $1,414,865
Goal: The goal of the study described herein is to determine the effectiveness of the use of the ReCell device over a widened STSG mesh in combination with INTEGRA will improve upon the current standard of care.
List of Specific Aims:

- Specific Aim 1: Assess the preliminary effectiveness of ReCell treatment of full-thickness wounds treated with INTEGRA MBWM compared to a control site.
- Specific Aim 2: Assess the long-term effectiveness of ReCell treatment of full-thickness wounds treated with INTEGRA MBWM compared to a control site.
- Specific Aim 3: Evaluate safety of ReCell treatment of full-thickness wounds treated with Integra MBWM compared to control site.

Role: Principal Investigator
Scientific/Budgetary Overlap: None

Pending Support
PI: Dr. Leon Nesti
Title: Clinical Evaluation of Decellularized Nerve Allograft with Autologous Bone Marrow Stem Cells to Improve Peripheral Nerve Repair and Functional Outcomes
Time Commitment:
Supporting Agency: CDMRP
Funding Agency's Procuring Contracting/Grants Officer:
Performance Period: 2015 - 2018
Level of Funding: $2,500,000
Project Goal:
Role: PI